

MAY - 5 2000

510(k) summary for the CARTO Mapping System

510(k) Notification submitted by: Biosense Webster, Inc.
3333 Diamond Canyon Rd.
Diamond Bar, CA 91765
USA
Phone: +1-800-729-9010
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Contact person: Amy Walters
Director of Regulatory Affairs

Proprietary device name: CARTO™ EP Navigation System

Classification name: Programmable diagnostic computer
(per 21 CFR 870.1425)

Common device name: Cardiac mapping system

Predicate device: CARTO mapping system
510(k) No. K993729

Manufacturer: Biosense Webster (Israel) Ltd.
POB 2009
Tirat HaCarmel, 39120
Israel

The CARTO mapping system is designed to acquire, analyze, and display electro-anatomical maps of the human heart. The maps are reconstructed using the combination of information gathered from the integration of intracardiac electrograms with their respective endocardial locations. In the CARTO mapping system the location information needed to create the cardiac maps is acquired simultaneously with the local electrogram using locatable-tip catheters equipped with a magnetic location sensor.

Currently, cardiac mapping is performed using a roving mapping catheter, a computerized mapping system, and fluoroscopy to determine the location of the tip of the mapping catheter. In the conventional procedure both the patient and the physician are exposed to harmful ionizing radiation during the course of the lengthy procedure. The CARTO mapping system enables cardiac mapping using a magnetic location technology, and may reduce exposure to dangerous ionizing radiation.

The CARTO mapping system complies with the following safety standards:

EN 60601-1/1990
EN 60601-1 A1/1993
EN 60601-1 A2/1995
EN 60601-2-27/1994

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The non-clinical bench and animal testing show that the device is as safe and as effective as the previously marketed device to which it is being compared and does not raise any new questions of safety or effectiveness.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 5 2000

Ms. Amy Walters
Director, Regulatory Affairs
Biosense Webster, Inc.
3333 Diamond Canyon Road
Diamond Bar, California 91765

Re: K000248
Trade Name: CARTO™ EP Navigation System
Regulatory Class: II (two)
Product Code: DQK
Dated: April 6, 2000
Received: April 7, 2000

Dear Ms. Walters:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

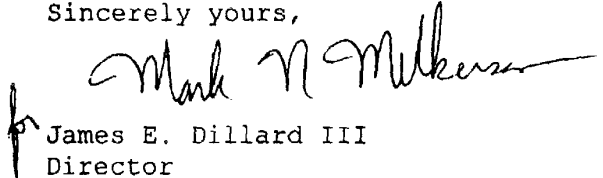
Page 2 - Ms. Amy Walters

for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Mulken", is written over the typed name "James E. Dillard III".

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and Radiological
Health

Enclosure

Indications for use statement

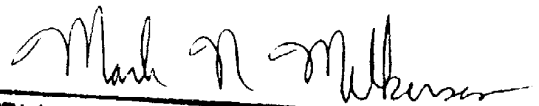
510(k) No: K000248/S1

Device Name: CARTO mapping system

Indications For Use:

The intended use of the CARTO mapping system is catheter-based cardiac mapping.

The CARTO mapping system allows real-time display of cardiac maps in a number of different formats. Maps may be displayed as cardiac electrical activation maps, cardiac electrical propagation maps, cardiac electrical potential maps, cardiac chamber geometry maps and cardiac impedance maps. The acquired patient signals, including body surface ECG and intracardiac electrograms may also be displayed in real time on the display screen.


for (Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K000248

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